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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ronald L Grudziecki
Burns Doane Swecker & Mathis
PO Box 1404
Alexandria, VA 22313-1404

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/15/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,541

Applicant(s)

AKIMOTO ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/07/2003 as Paper Number 13.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34, 36-43, 45-68 and 70-80 is/are pending in the application.
- 4a) Of the above claim(s) 15-29, 45-51, 59-64 and 74-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

- 1.. Applicants' amendment filed 03/10/2003 as paper Number 11 and Supplemental amendment filed April 07, 2003 as Paper Number 13 are acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Applicants' Declaration filed March 10, 2003 as Paper Number 12 is acknowledged and entered. However, with this declaration applicants should clearly indicate the purpose of filing said declaration and appropriate section under which said Declaration is filed.
3. Claims 35 and 69 have been cancelled.
4. Claims 1, 11, 34, and 58 have been amended.
5. Claims 1-34, 36-43, 45-68 and 70-80 are pending.
6. Claims 15-29, 45-51, 59-64 and 74-80 have been withdrawn as being non-elected claims (see Applicants' response filed June 21, 2002 as paper number 8 in response to restriction Requirement of May 21, 2002 (See Paper number 7 and Office Action mailed September 10, 2003 as Paper Number 9). Examiner suggests that to expedite prosecution, the non-elected claims cited *supra* be canceled in response to this Office action.
7. Claims 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 are examined on merits.

Claim Rejections - 35 U.S.C. § 101

8. Claim 11 is rejected under 35 U.S.C. § 101 for the reasons of record on page 3, item 10 of the Office Action mailed on 09/10/2002 as paper number 9 and reiterated as follows: Claim 11 is drawn to nonstatutory subject matter. As written, the claim is drawn to a biological material *per se*, which is a product of nature. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C. §101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Inoculant Co. 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980). The Examiner suggests that applicant use the language "an isolated, biologically pure microorganism" in connection with the microorganism to identify a product that is not found in nature.

Applicants' arguments regarding the rejections to Claims 1-3, 7-14, 34-36 and 52-58

under 35 U.S.C. § 101 in the Office Action mailed 09/10/2002 as paper Number 9 have been fully considered but are not deemed persuasive. Applicants argue that Claim 1 has been amended and therefore, all claims depending from Claim 1 automatically have the limitations from Claim 1. However, amended Claim 11 does not have this limitation and is therefore, still drawn to a non-statutory subject matter as discussed *supra* and in the previous Office action.

Claim Rejections - 35 U.S.C. § 112

9. Claims 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a composition obtained by culturing a microorganism, said microorganism is *Mortierella alpina* and more specifically strains *Mortierella alpina* IFO 8568 and mutants, namely, *Mortierella alpina* strains SAM 2241 and SAM 2242 obtained from said *Mortierella alpina* IFO 8568. The microorganism *Mortierella alpina* Strains SAM 2241 and Sam 2242 are essential to the invention recited in those claims. Those microorganisms must therefore, be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

Applicants' arguments regarding the rejections to Claims 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 under 35 U.S.C. § 112, first paragraph in the Office Action mailed 09/10/2002 as paper Number 9 have been fully considered but are not deemed persuasive. Applicants argue that microorganisms outlined *supra* have been deposited. However, the deposited microorganisms are *Mortierella elongata* SAM 0219 and *Mortierella alpina* SAM 2241, whereas the claimed invention is exemplified with and drawn to *Mortierella alpina* strains IFO 8568, SAM 2241 and SAM 2242. A deposit of *Mortierella alpina* IFO 8568 and SAM 2242 is still required under 35 U.S.C. § 112, first paragraph. Furthermore, applicants' Declaration filed April 7, 2003 as paper number 13 is deficient because it does not clearly state that the deposit was made according to criteria set forth in 37 C.F.R. §§ 1.801-1.809 (i.e., the deposit was made under the terms of Budapest Treaty at a recognized depository).

10. Claims 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for the demonstrated microorganisms, *Mortierella alpina* strains SAM 2241 and SAM 2242 that extracellularly secrete encapsulated lipid vesicles comprising within said vesicles "a lipid that contains unsaturated fatty acids", is not enabled for any and all microorganisms which extracellularly secrete encapsulated lipid vesicles as claimed (including any and all of the microorganisms recited on pages 9-10 of the instant specification).

Applicants have reasonably demonstrated that two mutant *Mortierella alpina* strains – i.e., SAM 2241 and SAM 2242, are capable of extracellularly secreting encapsulated lipid vesicles comprising therein a lipid that contains unsaturated fatty acids. However, the claims encompass any and all microorganisms having these characteristics which is clearly beyond the scope of the instantly claimed invention, especially since the art of mutation with respect to imparting particular characteristics/properties to such mutant strains is well known to be difficult and highly unpredictable (See, e.g., Demain et al., Manual of Industrial Microbiology and Biotechnology, 1986, American Society for Microbiology, page 188, Column 2, Lines 20-36).

Accordingly it would take undue experimentation without a reasonable expectation of success for one of ordinary skill in the art to isolate/obtain a microorganism having the instantly claimed characteristics other than the two demonstrated mutant *Mortierella alpina* strains – i.e., SAM 2241 and SAM 2242.

11. Claims 8-9, 38-39, 53, 56-57 and 70 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase "artificially treating" or "artificial treatment" in claims 8-9, 38-39, 53, 56-57 and 70 render those claims indefinite because the metes and bounds for the said phrase are not defined. Applicants should define the phrase "artificially treating" or "artificial treatment".

Applicants' arguments regarding rejections to Claims 8-9, 38-39, 53, 56-57 and 70 under 35 U.S.C. § 112, second paragraph in the Office Action mailed 09/10/2002 as paper Number 9 have been fully considered but are not deemed persuasive. Applicants argue that the phrases "artificially treating" or "artificial treatment" should be sufficiently clear to an

artisan of ordinary skill. Applicants further argue that said phrases have been clarified on Page 10, Line 32 to Page 11, Line 7 of the instant specification. However, Examiner respectfully submits that claims have to be clear within the claim language because even though claims are read in light of the specification, the specification language cannot be read into claims.

12. Claim 52 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The phrase "DHA" in claim 52 renders that claim unclear and therefore indefinite. The metes and bounds to distinguish this phrase are not established. Furthermore, abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.


CONCLUSION

13. No Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30A.M. to 6:00 P. M. (Eastern Standard or Daylight Saving time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196
July 14, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER